



## ENTITLEMENT OFFER TO RAISE \$7 MILLION

5 June 2017

### Transaction Highlights

- Fully underwritten entitlement offer to raise \$7m
- Funds used to complete recruitment of 240 patients for US FDA clinical trial
- Trial design and protocols approved by FDA
- Completion of US clinical trial expected in Q3 2018
- Commercialisation of Technegas in the US market expected to commence in Q4 2018, subject to successful trial and FDA approval
- US market opportunity of \$90m USD per annum

Cyclopharm Limited (**Company**) is pleased to announce that it is conducting a fully underwritten non-renounceable pro-rata entitlement offer to raise approximately \$7 million, before offer costs (**Entitlement Offer**).

Cyclopharm Managing Director, James McBrayer said that:

*“The funds raised will allow us to complete recruitment for our FDA approved US clinical trial. Having the trial design pre-approved by the FDA and the broadening of our recruitment criteria gives the Board a high level of confidence that we have substantially de-risked the regulatory uncertainty associated with the trial. We anticipate that the trial will be completed in Q3 2018 and we are aiming for FDA approval and full scale US commercialisation and revenues the following quarter. Given the rapid adoption of Technegas in Canada, the Board anticipates that similar rates of adoption can be achieved in the US market.”*

### Use of funds

Entitlement Offer proceeds will be used to complete recruitment of the 240 patients required for the FDA approved US clinical trial of Technegas across 10 to 15 locations, including a preliminary 40 patient clinical trial for submission to the FDA in Q1 2018.

### FDA Approved Clinical Trial

In order to mitigate regulatory risk the Company adopted the FDA Special Protocol Assessment (SPA) pathway for its US clinical trial. The SPA pathway provided the Company with the opportunity to reach agreement with the FDA on the overall protocol design (including entry criteria, dose selection, endpoints and planned analysis). The key benefits of the SPA pathway are the value of preliminary input from the FDA around trial design and eliminating the risk that clinical endpoints can be called into question at the time of the New Drug Application submission.

In order to further mitigate regulatory risk, the trial is designed on an ‘all comers basis’ meaning broad selection criteria which the company anticipates will accelerate completion of the trial in Q3 2018.



### Entitlement Offer Details

The Entitlement Offer will be open to shareholders of the Company with a registered address in Australia, New Zealand and the United Kingdom (**Eligible Shareholders**).

Under the Entitlement Offer, Eligible Shareholders can subscribe for 1 fully paid ordinary share (**New Share**) for every 6.8 existing shares in the Company held as at 7pm (Sydney time) on Thursday, 8 June 2017 (**Record Date**) at an issue price of \$0.80 per New Share.

The Entitlement Offer will be fully underwritten by Bell Potter Securities Limited.

### Additional New Shares

Eligible Shareholders may apply for up to \$15,000 worth of New Shares in excess of their entitlement (**Additional New Shares**). Additional New Shares will be sourced from entitlements that were not taken up under the Entitlement Offer and will not exceed the shortfall. The Directors reserve the right to allot and issue Additional New Shares in their absolute discretion and there is no guarantee that Eligible Shareholders will receive the number of Additional New Shares applied for, or any.

### Indicative timetable

Event	Date
Announcement of terms of the Entitlement Offer	Monday, 5 June 2017
Existing shares quoted on an 'ex-entitlement' basis	Wednesday, 7 June 2017
Record Date	7pm (Sydney time) Thursday, 8 June 2017
Entitlement Offer opens Entitlement Offer Booklet and acceptance forms despatched	Wednesday, 14 June 2017
Entitlement Offer closes	5pm (Sydney time) Friday, 23 June 2017
Announcement of shortfall (if any) under the Entitlement Offer	Wednesday, 28 June 2017
Allotment date of new shares issued under the Entitlement Offer	Friday, 30 June 2017
Despatch of holding statements for New Shares issued under the Entitlement Offer Normal trading of New Shares issued under the Entitlement Offer	Monday, 3 July 2017

The timetable is subject to change and the Company reserves the right to withdraw or vary the timetable for the offer without notice. In particular, the Company reserves the right to extend the closing date for the Entitlement Offer and to accept late applications whether generally or in particular cases.

### Investor presentation

A copy of the investor presentation follows.

**ENDS**

# Cyclopharm Limited

A profitable and growing market leader  
in nuclear medical imaging and lung healthcare

## **Capital Raising Investor Presentation**

5 June 2017



# Company Overview

# Company Overview

## Cyclopharm Limited (CYC) is a leading nuclear pharmaceuticals company

- A world leader in functional lung ventilation imaging technology with recurring consumables and capital equipment revenue streams
- A profitable and growing company with a history of dividend payments
- Lead product Technegas is currently sold in 56 countries with significant opportunity to expand into USA with FDA trial completion expected in Q3 2018
- Opportunity to broaden Technegas application beyond pulmonary embolism diagnosis into large addressable markets such as COPD and Asthma



Share Price (as at 2 June 17)	\$1.00
Shares on Issue	60.0 million
Market Capitalisation	\$60.0 million
Cash (31 Dec 16)	\$4.6 million

# Company Overview

## Cyclopharm's leading product is the *Technegas* technology system

- The Technegas proprietary technology provides high quality diagnostic functional lung imaging.
- Predominantly used to diagnosis the presence of blood clots in the lung otherwise known as Pulmonary Embolisms (PE), with advances in complementary technology the potential for use in other indications is rapidly evolving.
- In a clinical setting, the patient inhales, in only a few breaths, an ultrafine dispersion of Technegas particles. Once inhaled and deposited in the lungs, Technegas images are then captured by using conventional nuclear medicine scanning equipment.
- The Technegas images provide the clinician an understanding of how well the patient's lungs are functioning across a range of disease states.
- CYC sells the Technegas Generator to hospitals as a one-off capital item. Consumable components are inserted into the Technegas Generator which then produce the gas like particles that are inhaled by the patient. The consumables which deliver Technegas are single use items which are sold exclusively by CYC.

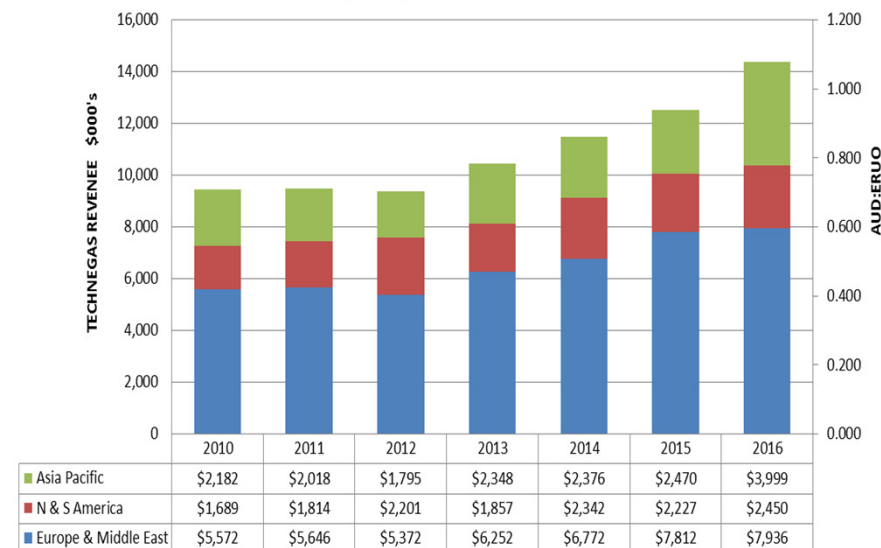


# Proven Market Adoption

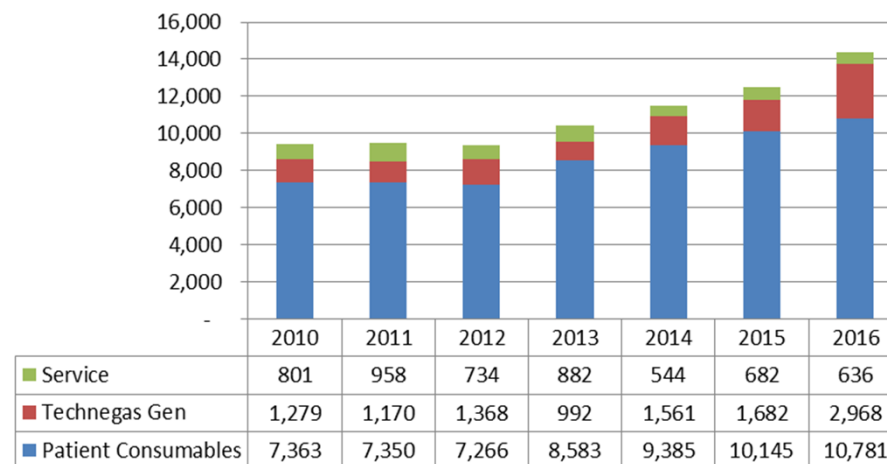
**Technegas is a substantially de-risked commercial proposition with significant upside in the US market**

- Total **global sales of \$77m** since 2010
- Technegas currently sold in **56 countries**
- Over **210,000 patient procedures** in 2016
- Over **3,700,000 patient procedures** since 1986
- **1,500 Technegas generators** sold globally
- **FY2016 Sales of \$14.4m and EBIT of \$1.4m**
- CYC is a growing, profitable and dividend paying company
- Stable gross margins of greater than 75%
- 79% of historical revenue is generated through recurring consumable sales

**Technegas Regional Revenue**



**Technegas Revenue by Category**



# Advantages of Technegas

## Technegas provides clinically superior outcomes to its competitors

- Better clinical results at a fraction of the high radiation doses used in CTPA (angiograms)
- No contraindications
- More accurate and sensitive measurement in diagnosing pulmonary embolism
- Effective when CTPA is contraindicated e.g. renal impairment
- Improved patient comfort and tolerance with only 3-4 breaths required for delivery
- Allows for 3D images and regional quantification
- Named as the preferred ventilation imaging agent of choice in the European Association of Nuclear Medicine Guidelines

## IP/Generic protection

- Technegas is a system - needs the generator, patient administrator set (PAS) and service capability
- R&D on 3rd generator generation underway set to extend IP protection

## Competitive Nuclear Medicine Products

Product	Comparison to Technegas
Xenon 133	<ul style="list-style-type: none"><li>▪ Patient has to continually re-breathe gas causing patient discomfort</li><li>▪ Can't provide 3D images</li><li>▪ Costly air-handling infrastructure required in order to administer</li></ul>
DTPA	<ul style="list-style-type: none"><li>▪ Inferior images in patients with obstructive lung disease (COPD)</li></ul>





# Capital Raising

# Entitlement Offer Summary

**Cyclopharm is undertaking a fully underwritten non-renounceable Entitlement Offer to raise approximately A\$7 million\* to fund an FDA approved phase 3 US clinical trial ...**

## Key offer details

<b>Use of funds</b>	<ul style="list-style-type: none"><li>• The funds raised under the Offer will be used<ul style="list-style-type: none"><li>• to recruit the 240 patients required for the US FDA trial of Technegas across 10 to 15 locations; and</li><li>• to complete a preliminary 40 patient clinical trial for submission to the FDA in Q1 2018</li></ul></li></ul>
<b>Structure</b>	<ul style="list-style-type: none"><li>• 1 for 6.8 non-renounceable Entitlement Offer to raise approximately \$7m<ul style="list-style-type: none"><li>• 8.8 million New Shares</li><li>• Fully underwritten</li></ul></li></ul>
<b>Offer Price</b>	<ul style="list-style-type: none"><li>• Offer price of \$0.80 per share<ul style="list-style-type: none"><li>• 20.0% discount to last close (2 June 2017 close \$1.00)</li><li>• 17.2% discount to 5-day VWAP of \$0.967</li><li>• 17.9% discount to TERP of \$0.974</li></ul></li></ul>
<b>Ranking</b>	<ul style="list-style-type: none"><li>• All new shares will be fully paid and rank equally with CYC's existing shares</li><li>• All new shares will be eligible to participate in the FY17 interim dividend payable in September 2017</li></ul>
<b>Offer jurisdictions</b>	<ul style="list-style-type: none"><li>• Registered addresses in Australia, New Zealand and UK</li></ul>
<b>Underwriter</b>	<ul style="list-style-type: none"><li>• Bell Potter Securities Limited</li></ul>

\*To eliminate currency risk funds will be converted to USD immediately following settlement of the transaction

# Investment Highlights

- **\$90m US market opportunity** - The US market opportunity for pulmonary embolism diagnosis is approximately USD\$90m representing 480,000 patient procedures p.a.
- **Clear path to US commercialisation** - Completion of the US clinical trial and FDA approval will clear the path for the immediate large scale commercialisation of Technegas across the US market
- **Trial design FDA approved** - The clinical trial design has been approved by the FDA substantially reducing the risk of any adverse regulatory obstacles during the approval process
- **Commencement of 240 patient trial** - The funds raised will facilitate the recruitment of the 240 patients required for the clinical trial across 10 to 15 sites
- **Commercial sales targeted to commence Q4 2018** - The Company anticipates that the clinical trial will be completed in Q3 2018 with the aim of achieving commercial US sales in Q4 2018
- **Guidance Affirmed** - Excluding the positive impact of the large Chinese order in FY16, the Board expects continuing modest growth in underlying Technegas volumes for FY17

# Timetable



## Entitlement Offer key dates

Entitlement Offer Announced	Monday, 5 June 2017
Ex-date for Entitlement Offer	Wednesday, 7 June 2017
Record Date for Entitlement Offer	Thursday, 8 June 2017
Entitlement Offer opens	Wednesday, 14 June 2017
Offer Booklet and Acceptance Forms sent to all Eligible Shareholders	Wednesday, 14 June 2017
Entitlement Offer closes	Friday, 23 June 2017
Allotment of shares issued under Entitlement Offer	Friday, 30 June 2017
Dispatch of holding statements	Monday, 3 July 2017
Expected date for trading of Entitlement Offer shares	Monday, 3 July 2017



# **FDA Trial and US Commercialisation**

# FDA Approved Trial Design

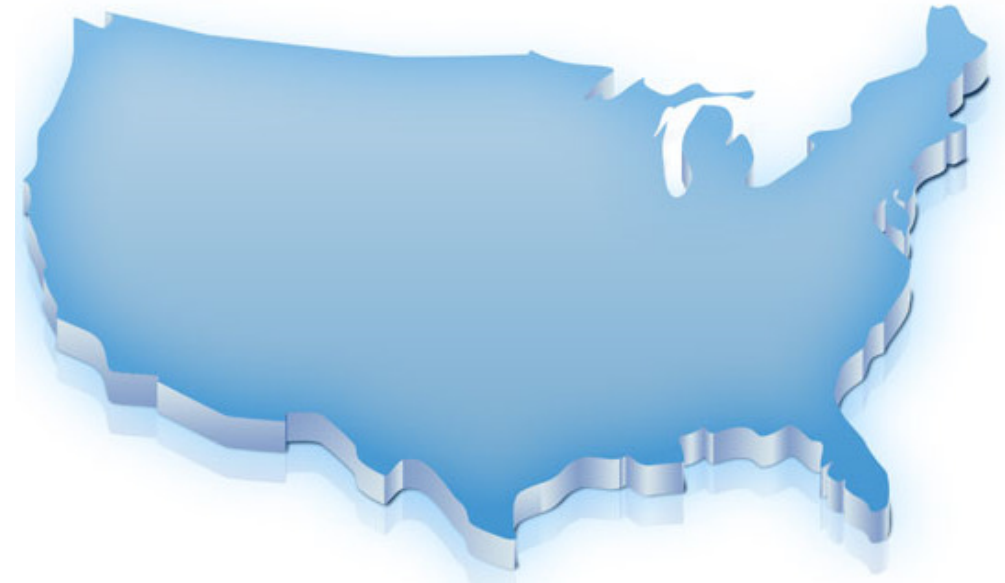
- **De-risked clinical trial strategy** - In order to mitigate regulatory risk the Company adopted the FDA Special Protocol Assessment (SPA) pathway for its US clinical trial
- **FDA approved trial design** - The SPA pathway provided the Company with the opportunity to reach agreement with the FDA on the overall protocol design (including entry criteria, dose selection, endpoints and planned analysis).
- **Regulatory risk substantially eliminated** - The key benefits of the SPA pathway are the value of preliminary input from the FDA around trial design and eliminating the risk that clinical endpoints can be called into question at the time of the New Drug Application submission.
- **Broad patient selection criteria** - The trial is designed on an 'all comers basis' meaning broad selection criteria which will facilitate the expeditious completion of the trial in Q3 2018.
- **Short timeframe to FDA approval and commercial launch** - The Company has diligently de-risked the FDA clinical trial process and looks forward to concluding the trial and obtaining FDA approval with the aim of commencing US commercialisation during Q4 2018

# Pathway to US commercialisation

- **Target preliminary study completion Q1 2018** - During Q1 2018 the Company aims to conclude a preliminary study of 40 patients and receive feedback from the FDA.
- **Target FDA Trial completion Q3 2018** - Assuming positive feedback from the preliminary study, the Company will continue with the comprehensive FDA trial which it anticipates will be completed during Q3 2018.
- **Target commercial launch Q4 2018** - Following the preliminary 40 patient study the Company will invest in Technegas inventory and, after successful completion of FDA trial and issue of FDA approval, target commercial launch in the US during Q4 2018
- **Market dominance in Canada** - The Company achieved market dominance in Canada (and a number of other markets) at gross margins of ~75% over approximately 10 years.
- **US market penetration** – Based on experience in other markets, the Company is targeting greater than 50% competitive product market conversion in the US over a period of 5 to 7 years.
- **Increased gross margin in US market** – Based on sale prices of existing competitive products, the Company expects to maintain or improve its historical gross margin on both consumable and capital equipment sales in the US Market.

# US Market Opportunity

- The USA represents the single largest market for Technegas with half of the world's nuclear medicine departments
- Target market for Technegas in the USA equates to ~480,000 patient procedures of the total 600,000 procedures conducted p.a. in that market (Current Rest of the World volumes for Technegas = 200,000 patients p.a.)
- Subject to a successful trial and FDA approval, the Company is targeting US commercialisation in Q4 2018
- First priority following USFDA approval is to repeat our Canadian experience by displacing Xe133 as the standard of care diagnostic product



**US Pulmonary Embolism market opportunity**  
**USD \$90m p.a.**

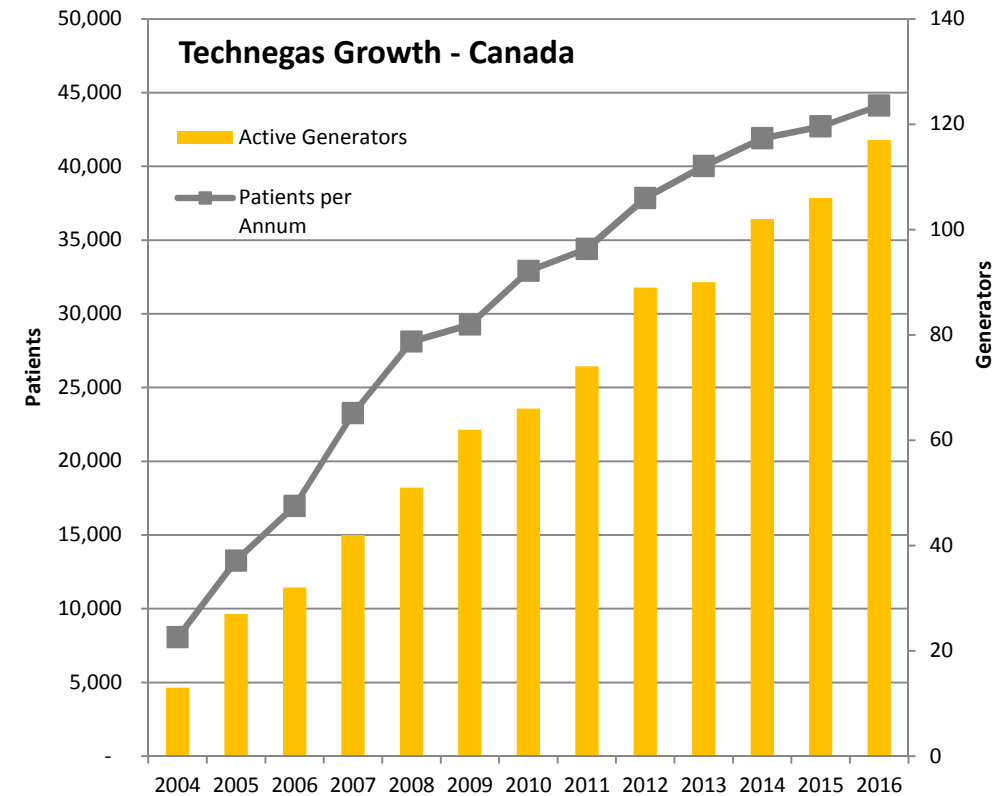


# Technegas – The Canadian Case Study

## Canada is Cyclopharm's largest single country market

- Market leader for diagnosing PE
- 13 consecutive years of PAS growth
- Represents a strong indicator of USA acceptance
- Xe-133 rapidly displaced by early adopters
- Direct correlation with the number of active generators and annual consumable sales
- Market driven by public healthcare sector
- Market launch initiated province by province, leveraging off pilot sites

## The Generator and Consumable Relationship





# Technegas Technology

# What is Technegas?

## **Technegas is the world leader in functional lung ventilation imaging.**

- Technegas is a structured ultra-fine dispersion of radioactive gas like substance which is inhaled by the patient. It allows imaging for evaluating functional ventilation.
- Primarily used to diagnose the presence of blood clots in lungs (Pulmonary Embolism)
- Produced by heating Technetium-99m in a carbon crucible for a few seconds at 2,750 degrees Celsius
- The resultant gas-like substance is produced in a Technegas generator
- The small size and hydrophobic properties together confirm ideal characteristics for gas-like behaviour on inhalation into the lungs
- Technegas, used in the ventilation part of the low radiation dose V/Q SPECT imaging, is cost-effective, simple to perform and accurate

### **Technegas is a System**

In order to deliver the best clinical outcomes, Technegas requires the combination of authorised:

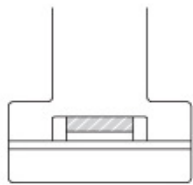
- ✓ Equipment and consumable sales and support
- ✓ Regulatory representation
- ✓ Technical provision of equipment installation and maintenance
- ✓ Applications education in the use of the Technegas technology

### **Technegas Consumable - Patient Administrator Set**

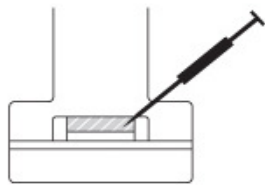


# Manufacture and Delivery of Technegas

## Manufacture

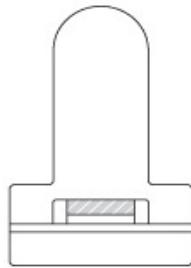


Turn on unit and argon flow to Generator.  
Insert crucible

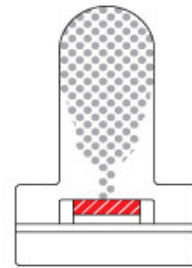


Moisten crucible with Ethanol.

Add 250 – 700 MBq Tc99m Sodium pertechnetate.



Close drawer and initiate simmer stage



Initiate burn sequence (2,700° C) to create Technegas  
Administer within 10 minutes of production

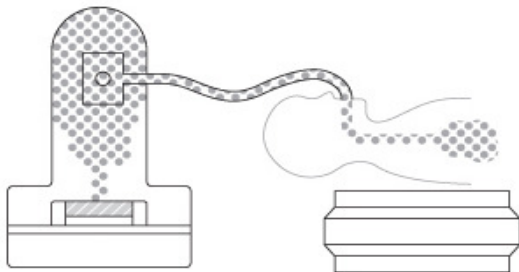
## Technegas



Technegas is composed of Tc-99m cores encapsulated within layers of graphite to form individual hexagonal plate-like particles.

These particles agglomerate to reach a dynamic equilibrium with regard to particle size distribution with a mean and median particle size between 100 to 200 nm.

## Delivery



Attach single use Patient-Administration Set and deliver Technegas to the patient

Technegas is inhaled by the patient until the required count rate is achieved in the lungs (1,000 - 2,500 cps equivalent to 15-37 MBq)





# Company Financials

# Historic Performance

**Cyclopharm's proven proprietary technology underpins accelerating commercial success and provides a foundation for further growth**

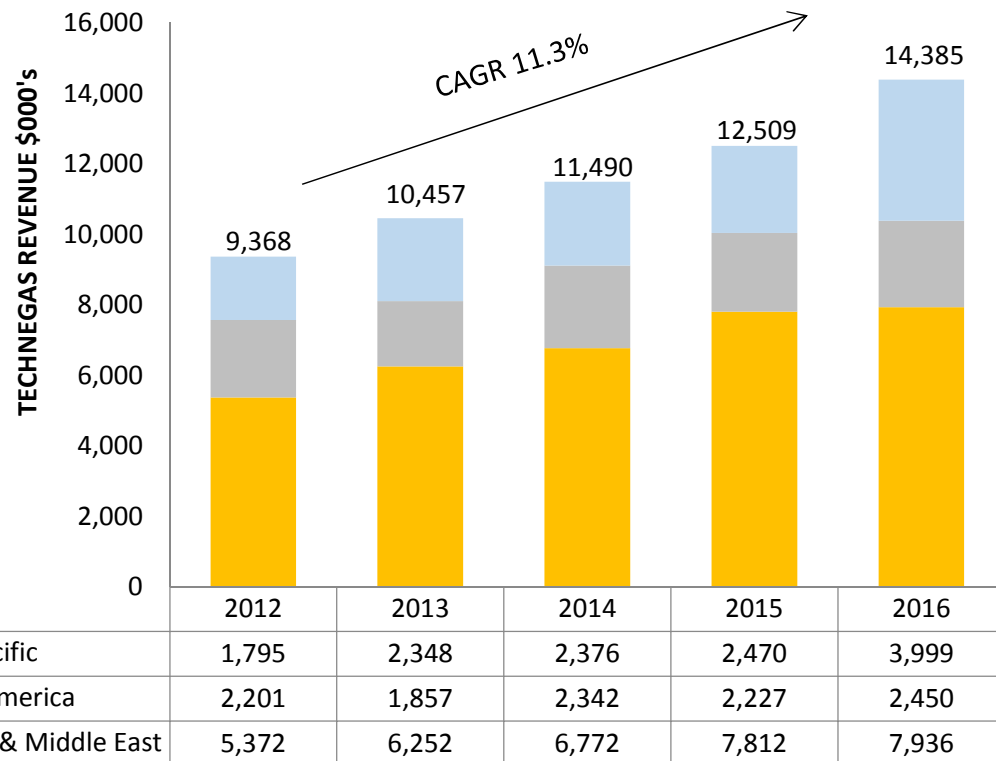
<i>Year ended 31 December (\$000's)</i>	2016	2015	% Change
<b>Technegas Results:</b>			
<b>Sales Revenue</b>			
PAS	10,782	10,145	6.3%
Generators/service	3,604	2,363	52.5%
<b>Total Sales</b>	<b>14,386</b>	<b>12,508</b>	15.0%
<b>Underlying EBITDA</b>	<b>3,438</b>	<b>2,980</b>	15.4%
Underlying EBITDA Margin	23.9%	23.7%	0.2%
FDA Expenses	(1,098)	(686)	60.0%
<b>EBITDA</b>	<b>2,340</b>	<b>2,294</b>	2.0%
D&A	(106)	(137)	22.6%
<b>EBIT</b>	<b>2,234</b>	<b>2,157</b>	3.6%

- FY16 revenue of \$14.4m and underlying EBIT of \$2.2m with no contribution from USA which represents over 50% of the Pulmonary Embolism world market
- A third consecutive year of record revenues in FY2016 assisted by the delivery in December 2016 of the single largest order placed for the China market

# Technegas Full Year Performance

## Third consecutive year of record underlying results

**Technegas Regional Revenue**



- Cyclopharm have delivered 4 year Revenue CAGR of 11% from Technegas Sales
- Europe is the largest regional market for Technegas
- In 2014 Canada became the largest single country market, surpassing France

# Group Balance Sheet

## Solid Financial Foundation to Leverage Growth Strategy

(\$000's)	Dec 2016	Cap Raising Impact	Pro Form Dec 2016
Cash	4,591	6,700	11,291
Other current assets	6,470		6,470
Non-current Assets	5,354		5,354
<b>Total Assets</b>	<b>16,415</b>		<b>23,115</b>
Current Liabilities	3,896		3,896
Borrowings	-		-
Non-current Liabilities	57		57
<b>Total Liabilities</b>	<b>3,953</b>		<b>3,953</b>
<b>Net Assets</b>	<b>12,462</b>		<b>19,161</b>

- **Debt free** – provides balance sheet and funding flexibility
- Funds raised under the Offer will be used to complete the FDA approved US clinical trial enrolment and preliminary trial submission to the FDA
- Underlying strong financial performance supports ongoing investment in R&D and expansion into new markets and indications





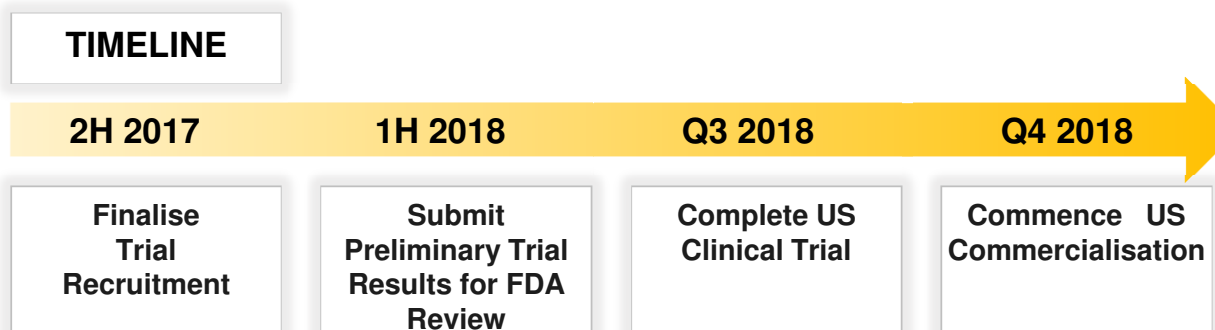
# Appendix

- Technegas FDA Trial Process and Design
- Ultralute™
- MMI
- Disclaimer

# Technegas FDA Clinical Trial Process and Design

## Study Specifics:

- Non-inferiority structural ventilation study comparing Xe133 vs. Technegas
- Pathway to approval requires a two part study
  - ✓ CYC 010 – Establishes the Inter & Intra reader variability for Xe133 – Completed
  - ✓ CYC 009 - Compares Xe133 with Technegas requiring patient recruitment – SPA Approved
- Total estimated trial cost \$7.5 million USD with \$2.4 m AUD spent to date
- Assumes 240 patient study at 15 clinical sites
- CYC will complete a preliminary 40 patient trial for submission to the FDA in Q1 2018





## Innovative, first-in-class, disruptive, proprietary technology used to improve radiopharmaceutical manufacturing efficiency and deliver health care cost effectiveness



Ultralute™

- **Extension of Generator life** – the Ultralute will extend the effective use of an Mo99 generator by up to 50%
- **Reduced purchase volumes** – Allows the user to purchase a smaller (lower cost) Mo99 Generator
- **Cost effective** - Provides a saving of between 30% to 40% in the cost of Tc-99m
- **Large market** - there are over 5,000 Mo99 generators sold worldwide each week.
- **Commercialisation** - Sales expected to commence H2 2017
- **Strong IP** - Patents secured in 2014
- **Supportive peak body** – Strong relationship with the International Atomic Energy Association (IAEA)
- **Established clinical trial strategy** - Multi-centre multi-country trial planned in conjunction with the IAEA

# Macquarie Medical Imaging



- Joint venture with:
  - 50% Alfred Health Solutions
  - 30% Macquarie University
  - 20% Cyclopharm
- Comprehensive suite of imaging modalities
- State of the art research platform
- Growth and profitability linked to ramp-up of Macquarie University Hospital
- EBIT positive since 2014
- Sales revenue increased 8% in 2016 as outpatient initiatives implemented at Macquarie University Hospital take effect
- Satellite Outpatient Clinic opened in 2H 2016 at nearby Macquarie Shopping Center





## Disclaimer

Certain views expressed here contain information derived from publicly available sources that have not been independently verified.

The presentation include certain statements, estimates and projections with respect to the anticipated future financial performance of Cyclopharm Limited and as to the markets for the company's products. Such statements, estimates and projections reflect various assumptions made by the directors concerning anticipated results, which assumptions may or may not prove to be correct. Cyclopharm Limited has not sought independent verification of information in this presentation..

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All references to dollars unless otherwise specified are to Australian dollars.

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